

# A randomised controlled trial to assess the efficacy of Laparoscopic Uterosacral Nerve Ablation (LUNA) in the treatment of chronic pelvic pain

<b>Submission date</b> 08/10/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/10/2002	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 03/09/2009	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Khalid Khan

### Contact details

Academic Department of Obstetrics and Gynaecology  
Birmingham Women's Hospital  
Metchley Park Road  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TG

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

LUNA

## Study objectives

1. To test the hypothesis that in women with chronic pelvic pain in whom diagnostic laparoscopy reveals either no pathology or mild endometriosis (American Fertility Society [AFS] score less than or equal to 5) LUNA alleviates pain and improves life quality at 12 months (principal objective)
2. To test the hypothesis that response to LUNA differs according to the site and cause of the pain by two secondary analyses:
  - 2.1. Women with central pain
  - 2.2. Women with no visible pathology
3. To explore the variation in LUNA's effectiveness and side effects at different periods of follow-up (3 and 6 months and 1, 2, 3, 5 and 10 years)

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Chronic pelvic pain in women

## Interventions

1. Diagnostic laparoscopy plus uterosacral nerve ablation (experimental group)
2. Laparoscopy without pelvic denervation (control group)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/09/2004

**Completion date**

01/09/2005

**Eligibility****Key inclusion criteria**

New patients presenting to the gynaecology outpatient clinic with pelvic pain (cyclical or non-cyclical) and/or dyspareunia, and requiring diagnostic laparoscopy for evaluation of these conditions, will be invited to participate.

**Inclusion criteria:**

1. Pelvic pain of longer than 6 month duration
2. Pain located within the true pelvis or between and below the anterior iliac crests
3. Associated functional disability
4. Lack of response to medical treatment
5. Diagnostic laparoscopy planned

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

420

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/09/2004

**Date of final enrolment**

01/09/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Academic Department of Obstetrics and Gynaecology**

Birmingham

United Kingdom

B15 2TG

## **Sponsor information**

**Organisation**

University of Birmingham (UK)

**Sponsor details**

Edgbaston

Birmingham

England

United Kingdom

B15 2TT

+44 (0)121 414 3344

postmaster@bham.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.bham.ac.uk/>

**ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Wellbeing (UK) (ref: CF/371)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	08/12/2003		Yes	No
<a href="#">Results article</a>	results	02/09/2009		Yes	No